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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,658	09/14/2000	Andrew D. Ellington	TEXAS-11145	9207

23535 7590 02/05/2008

MEDLEN & CARROLL, LLP
101 HOWARD STREET
SUITE 350
SAN FRANCISCO, CA 94105

EXAMINER	
GIBBS, TERRA C	
ART UNIT	**PAPER NUMBER**
1635	
MAIL DATE	**DELIVERY MODE**
02/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/661,658	ELLINGTON ET AL.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2008 and 06 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 September 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: sequence alignments #1, 2, and 3.

DETAILED ACTION

Notice of Rescinded Abandonment

A Notice of Abandonment was filed and made of record on August 8, 2007. Applicants filed a petition under 37 CFR 1.137(b) to revive the instant application. Applicant's petition was granted. It this regard, the Notice of Abandonment mailed August 8, 2007 has been rescinded and Applicant's Amendment and Remarks filed August 6, 2007 have been entered on the record.

Claims 7 and 21 have been amended.

Claims 7 and 21 are pending in the instant application.

Claims 7 and 21 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Drawings

In the previous Office Action mailed February 1, 2007, the drawings filed on September 14, 2000 were objected to because the description of the drawings indicated that such material may very well be critical to determining whether there exists adequate description and enablement of the instant invention. **This objection is withdrawn** in view of Applicant's Amendment and Remarks filed August 6, 2007. Specifically, the Examiner is withdrawing this objection in view of Applicant's submission of a larger print version for Figure 1 and higher resolution drawings for Figures 2a and 2b.

Specification

In the previous Office Action mailed February 1, 2007, the disclosure was objected to because the specification made reference to "Figure 3a", "Figure 3b", and "Figure 4a", where only "Figure 3" and "Figure 4" were disclosed in the Drawings section of the instant specification. **This objection is withdrawn** in view of Applicant's Amendment and Remarks filed August 6, 2007. Specifically, the Examiner is withdrawing this objection in view of Applicant's submission of Figures 3a and 3b in the Drawings and Applicant's removal of "Figure 4a" from the Specification.

It is noted that the in the previous Office Action mailed February 1, 2007, it was indicated that claims 7 and 21 were free of the prior art (see the previous Office Action mailed February 1, 2007 at page 4). However, after careful reconsideration of the claims and after a new sequence search, the following new rejection(s) are made of record:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,322,971 ('971).

Claim 7 is drawn to a regulatable aptazyme oligonucleotide comprising a Group I intron oligonucleotide and an aptamer oligonucleotide, wherein the kinetic parameters of the Group I intron oligonucleotide vary in response to the interaction of an allosteric effector molecule with the aptamer oligonucleotide and wherein the aptazyme comprises SEQ ID NO:2, or an oligonucleotide sequence that hybridizes under stringent conditions to a hybridization probe, the nucleotide sequence of which comprises SEQ ID NO:2, or an oligonucleotide that is complementary or antisense to such a probe. Claim 21 is drawn to an allosterically regulatable aptazyme oligonucleotide comprising a Group I intron oligonucleotide and an aptamer oligonucleotide, wherein the kinetic parameters of the Group I intron oligonucleotide vary in response to the interaction of an allosteric effector molecule with the aptamer oligonucleotide and wherein the aptazyme comprises SEQ ID NO:2, or an oligonucleotide sequence that hybridizes under stringent conditions to a hybridization probe, the nucleotide sequence of which comprises SEQ ID NO:2, or an oligonucleotide that is complementary or antisense to such a probe.

'971 discloses SEQ ID NO:16, which is a 12-mer oligonucleotide that is predicted to be 1 of 4 strands in a mixture of strand sets (see Figure 22A). '971 also discloses that each strand in a mixture can be made to hybridize to other nucleic acids (see

column 15, lines 15-18). It is noted that SEQ ID NO:16 is 100% complementary to nucleotides 76-87 of SEQ ID NO:2 (see attached sequence alignment #1). It is also noted that Applicant's specification at page 17, lines 5-7 discloses, "The term "Hybridize" as used herein, refers to any process by which a strand of nucleic acid binds with a complementary strand through base pairing". Further, the specification discloses, "With "high stringency" conditions, nucleic acid base pairing will occur only between nucleic acid fragments that have a high frequency of complementary base sequences" (see last paragraph bridging pages 19 and 20). Given the high degree of complementary between SEQ ID NO:16 of '971 and SEQ ID NO:2 of Applicant's invention, it is the Examiner's position that SEQ ID NO:16 of '971 would "hybridize under stringent conditions" to SEQ ID NO:2 of Applicant's invention as claimed.

Therefore, absent evidence to the contrary, claims 7 and 21 are anticipated by U.S. Patent No. 6,322,971.

******

Claims 7 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,616,488 ('488).

'488 discloses SEQ ID NO:449, which is a mouse IL-5 hammerhead ribozyme sequence targeted to IL-5 (see Table IV at columns 21 and 22). It is noted that SEQ ID NO:449 is 93% complementary to nucleotides 31-44 of SEQ ID NO:2, as the complementation contains only one mismatch (see attached sequence alignment #2). Given Applicant's specific definitions of "Hybridize" and "High stringency conditions" in

the instant disclosure, and given the high degree of complementary between SEQ ID NO:449 of '488 and SEQ ID NO:2 of Applicant's invention, it is the Examiner's position that SEQ ID NO:449 of '488 would "hybridize under stringent conditions" to SEQ ID NO:2 of Applicant's invention as claimed.

Therefore, absent evidence to the contrary, claims 7 and 21 are anticipated by U.S. Patent No. 5,616,488.

******

Claims 7 and 21 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 9965928-A2 ('928). '928 discloses and claims Tag #3736, which is a tag corresponding to distinct transcripts downregulated in metastatic breast tumor cells (see Tag #3736, pg. 158, and claims 1 and 2). It is noted that Tag #3736 is 100% complementary to nucleotides 101-110 of SEQ ID NO:2 (see attached sequence alignment #3). Given Applicant's specific definitions of "Hybridize" and "High stringency conditions" in the instant disclosure, and given the high degree of complementary between Tag #3736 of '928 and SEQ ID NO:2 of Applicant's invention, it is the Examiner's position that Tag #3736 of '928 would "hybridize under stringent conditions" to SEQ ID NO:2 of Applicant's invention as claimed. It is noted that Tags #4122, #2053, #4122, #5134, #5418, #5432, #3032, #1581, #3939, #2137, #1561, and #4852 also "hybridize under stringent conditions" to SEQ ID NO:2 of Applicant's invention as claimed.

Therefore, absent evidence to the contrary, claims 7 and 21 are anticipated by WO 9965928-A2.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the

Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

tcg
January 30, 2008

/Terra Cotta Gibbs/

Sequence alignment #3

RESULT 3
AAZ84502/c
ID AAZ84502 standard; DNA; 10 BP.
XX
AC AAZ84502;
XX
DT 07-APR-2000 (first entry)
XX
DE Metastatic breast tumour cell downregulated transcript tag #3736.
XX
KW Human; metastatic breast tumour tissue; breast cancer; tag; primer;
KW non-metastatic breast tumour tissue; gene therapy; anticancer;
KW antimetastatic; vaccine; diagnosis; ss.
XX
OS Homo sapiens.
XX
PN WO9965928-A2.
XX
PD 23-DEC-1999.
XX
PF 18-JUN-1999; 99WO-US013647.
XX
PR 19-JUN-1998; 98US-0089853P.
PR 19-JUN-1998; 98US-0089997P.
PR 19-JUN-1998; 98US-0090039P.
PR 19-JUN-1998; 98US-0090040P.
PR 19-JUN-1998; 98US-0090041P.
XX
PA (GENZ) GENZYME CORP.
PA (ROBE/) ROBERTS B L.
PA (SHAN/) SHANKARA S.
XX
PI Roberts BL, Shankara S;
XX
DR WPI; 2000-106079/09.
XX
PT Isolated polynucleotides differentially expressed between metastatic and
PT non-metastatic breast cancer cells, useful for diagnosis, prevention and
PT treatment of cancer.
XX
PS Claim 1; Page 158; 219pp; English.
XX
CC AAZ80767 to AAZ83941 represent tags corresponding to distinct transcripts
CC that are preferentially transcribed in the metastatic breast tumour
CC tissue (i.e. are upregulated in metastatic breast tumour cells). AAZ83942
CC to AAZ86677 represent tags corresponding to distinct transcripts that are
CC preferentially transcribed in the primary or non-metastatic breast tumour
CC tissue (i.e. are downregulated in metastatic breast tumour cells). These
CC transcripts can be used for diagnosis, prognosis, monitoring and
CC treatment of breast cancer, particularly where metastatic. Diagnosis is
CC by standard immunoassays or hybridisation/amplification reactions.
CC Compounds that modulate expression of the transcripts are potentially
CC useful for treatment of (metastatic) breast cancer, while promoters from
CC the transcripts are used to direct expression, in selected cell types, of
CC e.g. therapeutic genes (also ribozymes or antisense sequences),
CC particularly an antigen-encoding sequence for use in gene or cell-based

CC vaccines. Polypeptides encoded by the transcripts are also useful in
CC vaccines; for diagnosing breast cancer and for raising specific
CC antibodies (Ab). Ab are used to detect the polypeptides or as therapeutic
CC agents. Host cells that produce the polypeptides can be used to expand
CC and isolate populations of educated, antigen-specific immune effecter
CC cells, e.g. cytotoxic T lymphocytes, and these used for adoptive
CC immunotherapy
XX
SQ Sequence 10 BP; 3 A; 3 C; 1 G; 3 T; 0 U; 0 Other;

Query Match 7.6%; Score 10; DB 3; Length 10;
Score over Length 100.0%;
Best Local Similarity 100.0%; Pred. No. 1.4e+07;
Matches 10; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

```
Qy        101 TTGGCAGATA 110
              ||||||||||
Db         10 TTGGCAGATA 1
```

Sequence alignment #2

```
RESULT 34
US-08-319-492B-449/c
; Sequence 449, Application US/08319492B
; Patent No. 5616488
;  GENERAL INFORMATION:
;    APPLICANT:  Sullivan, Sean M.
;    APPLICANT:  Draper, Kenneth G.
;    APPLICANT:  McSwiggen, James
;    APPLICANT:  Stinchcomb, Dan T.
;    TITLE OF INVENTION:  RIBOZYME TREATMENT OF DISEASES
;    TITLE OF INVENTION:  OR CONDITIONS RELATED TO LEVELS
;    TITLE OF INVENTION:  OF IL-5
;    NUMBER OF SEQUENCES:  751
;    CORRESPONDENCE ADDRESS:
;      ADDRESSEE:  Lyon & Lyon
;      STREET:  633 West Fifth Street
;      STREET:  Suite 4700
;      CITY:  Los Angeles
;      STATE:  California
;      COUNTRY:  U.S.A.
;      ZIP:  90071
;    COMPUTER READABLE FORM:
;      MEDIUM TYPE:  3.5" Diskette, 1.44 Mb
;      MEDIUM TYPE:  storage
;      COMPUTER:  IBM Compatible
;      OPERATING SYSTEM:  IBM P.C. DOS 5.0
;      SOFTWARE:  Word Perfect 5.1
;    CURRENT APPLICATION DATA:
;      APPLICATION NUMBER:  US/08/319,492B
;      FILING DATE:  October 7, 1994
;    PRIOR APPLICATION DATA:
;    PRIOR APPLICATION DATA:  including application
;    PRIOR APPLICATION DATA:  described below:                Two
;      APPLICATION NUMBER:  08/008,895
;      FILING DATE:  January 19, 1993
;      APPLICATION NUMBER:  07/989,849
;      FILING DATE:  December 7, 1992
;    ATTORNEY/AGENT INFORMATION:
;      NAME:  Warburg, Richard
;      REGISTRATION NUMBER:  32,327
;      REFERENCE/DOCKET NUMBER:  209/276
;    TELECOMMUNICATION INFORMATION:
;      TELEPHONE:  (213) 489-1600
;      TELEFAX:  (213) 955-0440
;      TELEX:  67-3510
;  INFORMATION FOR SEQ ID NO:  449:
;    SEQUENCE CHARACTERISTICS:
;      LENGTH:  15 base pairs
;      TYPE:  nucleic acid
;      STRANDEDNESS:  single
;      TOPOLOGY:  linear
US-08-319-492B-449

  Query Match             9.5%;  Score 12.4;  DB 2;  Length 15;
  Score over Length      82.7%;
  Best Local Similarity  92.9%;  Pred. No. 5.8e+05;
  Matches   13;  Conservative    0;  Mismatches    1;  Indels    0;  Gaps    0;
```

```
Qy          31 TCTATCTAAACGGG 44
               ||||||||||| |||
Db          15 TCTATCTAAAGGGG 2
```

Sequence alignment #1

```
RESULT 1
US-09-164-249B-16/c
; Sequence 16, Application US/09164249B
; Patent No. 6322971
; GENERAL INFORMATION:
;  APPLICANT: Chetverin, Alexander B.
;  APPLICANT:  Kramer, Fred Russel
;  TITLE OF INVENTION: NOVEL OLIGONUCLEOTIDE ARRAYS AND THEIR USE FOR SORTING,
;  TITLE OF INVENTION:  ISOLATING, SEQUENCING, AND MANIPULATING NUCLEIC ACIDS
;  FILE REFERENCE: 07763-004003
;  CURRENT APPLICATION NUMBER: US/09/164,249B
;  CURRENT FILING DATE:  1998-09-30
;  PRIOR APPLICATION NUMBER: US 08/473,010
;  PRIOR FILING DATE: 1995-06-07
;  PRIOR APPLICATION NUMBER: US 08/247,530
;  PRIOR FILING DATE: 1994-05-23
;  PRIOR APPLICATION NUMBER: US 07/838,607
;  PRIOR FILING DATE: 1992-02-19
;  NUMBER OF SEQ ID NOS: 18
;  SOFTWARE: FastSEQ for Windows Version 3.0
; SEQ ID NO 16
;   LENGTH: 12
;   TYPE: DNA
;   ORGANISM: Artificial Sequence
;   FEATURE:
;   OTHER INFORMATION: Synthetically derived DNA
US-09-164-249B-16

  Query Match             9.2%;  Score 12;  DB 3;  Length 12;
  Score over Length     100.0%;
  Best Local Similarity 100.0%;  Pred. No. 7.5e+05;
  Matches   12;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          76 TTATACCAGCAT 87
               ||||||||||||
Db          12 TTATACCAGCAT 1
```